

# Breathe Easier Alliance of Alabama

(BEAA)



The Breathe Easier Alliance of Alabama is an advocacy group focused on legislation affecting tobacco harm reduction for adults via personal vaporizers which are shown to reduce the morbidity and mortality associated with smoking.

# Who We Are

- BEAA membership is comprised of responsible business owners who understand that exceptional accountability and high standards are vital to gaining acceptance of those who believe the industry is driven or influenced by big tobacco.
- The vaping industry in Alabama is comprised of over 300 small businesses that employ over 2000 people, all while facilitating a reduced-harm alternative for millions of tobacco users.
- BEAA members alone include well over 50 small vape related businesses, employing over 250 employees utilizing some 50,000 square feet of retail space with taxable sales totaling over \$25,000,000.00.
- The vapor products industry is the epitome of the American Dream; We are not huge corporations with endless resources. I as well as many others have risked our homes, retirement and everything that we have for a chance at the American Dream. We are the entrepreneurs and visionaries on which this industry has thrived. We work seventy and eighty hours a week for something we feel passionately about. We have grown organically and become a vibrant and multibillion-dollar industry that constantly strives to be more and more creative and innovative in tobacco harm reduction.

# Pre-Market Tobacco Approval Application Process

- The FDA has estimated the cost of applying for a Pre-Market Tobacco Approval for each vapor product at 5,000 hours and \$333,554.
- These estimates are also totally unrealistic, as experts estimate the actual cost of completing an application to be more like \$3.3 million, and could be more like \$33 million per SKU.
- The cost alone will preclude any small or even reasonable sized company from applying thus leaving the market wide open to big tobacco and effectively decimating the small business owners.
- The FDA has openly admitted that the proposed rule would have a significant economic impact on “small entities”. At no time do they appear to consider the benefits these small businesses bring to their communities by way of employment, sales tax, retail space rental and most importantly offering a better alternative to combustible cigarettes.

Table 1  
Smokers Represent Significantly Larger Proportion of  
Medicaid Recipients than General Population

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2011											
Percent Smokers Medicaid Enrollment		Number of Smokers on Medicaid		Number of Smokers on Medicaid Enrollment		Lost Productivity Premature Death		Healthcare Costs		Total Smoking Costs	
State	General Population	Medicaid Enrollment	Total	Medicaid Enrollment	Total	State	State	State	State	State	State
United States	3.1%	1.2% (Median)	68,321,615	86,161,329	154,490	United States	117,1	67,5	184,6	116,4	30,0
Alabama	24.3%	22.9%	935,313	45,922	1,047	Alabama	27	12	39	17	5,6
Alaska	68%	19.2%	935,419	914,810	1,047	Alaska	02	02	03	07	0.7
Arizona	49%	27.8%	777,333	470,030	1,047	Arizona	19	13	32	19	3.1
Arkansas	54%	15.3%	115,601,583	3,177,260	1,047	Arkansas	17	05	24	11	1.1
California	49%	15.3%	417,335	733,345	1,047	California	96	57	152	116	26.9
Colorado	61%	16.3%	179,294	23,225	1,047	Colorado	13	12	23	16	4.1
Connecticut	49%	21.7%	357,854	87,771	1,047	Connecticut	12	07	18	15	3.6
Delaware	58%	21.7%	329,173	1,764,420	1,047	Delaware	04	02	06	04	0.4
Florida	49%	21.2%	1,935,269	808,115	1,047	District of Columbia	02	01	03	01	0.1
Georgia	61%	16.5%	194,350	513,629	1,047	Florida	79	41	123	73	19.6
Hawaii	61%	17.7%	409,486	253,663	1,047	Georgia	37	14	62	29	9.0
Idaho	62%	20.9%	940,614	1,682,556	1,047	Hawaii	04	02	05	04	0.4
Illinois	58%	25.8%	325,521	821,188	1,047	Idaho	26	04	03	03	0.3
Indiana	68%	25.8%	1,205,205	312,116	1,047	Illinois	50	29	79	46	12.7
Iowa	61%	20.4%	344,620	312,116	1,047	Indiana	39	21	51	26	7.5
Kansas	54%	22.0%	363,755	196,238	1,047	Iowa	12	05	19	11	2.0
Kentucky	65%	25.0%	1,085,540	69,2796	1,047	Kansas	10	06	16	10	1.6
Louisiana	43%	25.7%	329,869	356,364	1,047	Kentucky	26	13	39	16	3.7
Maine	63%	22.9%	940,614	208,340	1,047	Louisiana	24	09	32	18	3.1
Maryland	51%	19.1%	100,346	314,809	1,047	Maine	06	03	09	07	1.6
Massachusetts	53%	18.2%	1,160,611	597,444	1,047	Maryland	21	13	36	21	5.6
Michigan	64%	23.3%	1,085,540	2,365,377	1,047	Massachusetts	23	13	34	37	11.5
Minnesota	54%	19.1%	989,620	344,384	1,047	Michigan	45	24	70	40	11.0
Mississippi	35%	26.0%	775,314	271,393	1,047	Minnesota	15	15	30	23	5.4
Missouri	66%	25.5%	1,116,505	733,343	1,047	Mississippi	16	07	24	10	3.5
Montana	70%	21.1%	136,447	95,559	1,047	Missouri	30	15	43	27	7.2
Nebraska	64%	20.0%	35,000	18,176	1,047	Montana	03	02	06	04	0.9
Nevada	62%	21.9%	363,335	235,231	1,047	Nebraska	06	05	11	05	1.6
New Hampshire	59%	19.4%	15,215,213	13,177,736	1,047	Nebraska	06	05	11	05	1.6
New Jersey	76%	18.8%	1,504,257	469,533	1,047	Nevada	11	05	27	09	2.6
New Mexico	50%	21.1%	151,521	35,511	1,047	New Hampshire	03	03	08	06	1.4
North Dakota	63%	20.0%	4,421,332	2,927,446	1,047	New Jersey	29	15	43	27	12.6
Ohio	63%	25.1%	1,592,341	1,192,341	1,047	New Mexico	05	04	09	06	1.5
Oklahoma	58%	26.1%	1,592,341	1,047,330	1,047	New York	69	39	95	54	20.6
Oregon	67%	19.7%	4,996,318	2,148,117	1,047	North Carolina	43	21	63	34	9.7
Pennsylvania	70%	22.8%	2,443,909	1,710,736	1,047	North Carolina	13	06	21	13	3.4
Rhode Island	48%	20.0%	22,041	10,130	1,047	Pennsylvania	54	32	65	37	14.2
South Carolina	41%	23.1%	2,576,233	1,642,216	1,047	Rhode Island	04	04	07	04	1.3
South Dakota	63%	23.1%	1,504,257	469,533	1,047	South Carolina	02	02	06	03	0.7
Tennessee	69%	23.0%	1,546,356	495,430	1,047	South Dakota	57	29	86	52	13.9
Utah	67%	20.9%	1,488,267	465,544	1,047	South Dakota	23	10	33	16	4.9
Vermont	64%	19.2%	1,592,341	1,192,341	1,047	Tennessee	03	02	05	03	0.8
Virginia	58%	18.8%	3,666,271	1,977,86	1,047	Tennessee	36	17	53	26	7.9
Washington	63%	23.1%	1,294,799	814,463	1,047	Texas	79	49	128	76	20.4
West Virginia	67%	19.1%	184,058	12,339	1,047	Utah	04	03	07	04	1.1
Wisconsin	62%	23.0%	76,372	47,351	1,047	Vermont	139	62	193	103	13.9
Wyoming	51%	20.8%	1,016,419	389,233	1,047	Virginia	02	01	04	03	0.7
Wyoming	51%	20.8%	1,488,267	465,544	1,047	Washington	29	20	45	25	7.5
Wyoming	51%	20.8%	91,331	1,371,937	1,047	West Virginia	21	13	34	24	3.7
Wyoming	51%	20.8%	417,128	275,536	1,047	West Virginia	12	05	20	11	2.5
Wyoming	51%	20.8%	76,372	47,351	1,047	Wisconsin	70,96	12,339	93	52	9.3
Wyoming	51%	20.8%	120,89	355,663	1,047	Wyoming	525	163	55	55	5.5

# FDA Deeming Regulations

- The FDA admits that not regulating new products like e-cigarettes may induce people to switch to products that the FDA do not regulate at all or with the same “stringency”. So not regulating would imply a benefit and the proposed rule will cause harm.
- In the RIA Benefit Analysis, FDA anticipates that “the largest benefit of the proposed provisions would be the improvements in health and life expectancy resulting from reduction in the use of combustible tobacco products deemed under this proposed rule” These benefits will be reduced by the simple fact that electronic cigarettes are not combustible tobacco products and provide a safer alternative.
- In section 2(b) of the RIA, “Electronic Cigarettes and Other Non-combustible, Novel Tobacco Products” FDA plainly states: “The benefits of including electronic cigarettes in this proposed rule are unknown and therefore cannot be quantified (page 19)

# Conclusion

- Ultimately, the FDA not having regulatory power over the electronic cigarette industry would be ideal for business owners and consumers alike. We are not against reasonable, rational regulation however being lumped together with combustible cigarettes does not allow for our unique industry to flourish nor does it recognize the significant health benefits to consumers having access to a variety of tobacco harm reduction options and devices.
- Should the FDA move forward with full PMTA, we would hope the industry would have a minimum of 2 to 3 years to comply with requirements, once the requirements are clearly defined.
- Only 2-3 companies marketed vapor products before the grandfather date of February 15, 2007 guaranteeing Substantial Equivalence (SE) Reports cannot be submitted to the FDA, creating a de-facto ban of >99.9% of the vapor product manufacturers in the US. Further the SE process is opaque and entirely arbitrary, denying participants the ability to pre-plan, coordinate, or ensure they could comply (if it were ever available to them). Please support H.R. Bill 2058
- Our industry has been on notice for over a year that these regulations are coming and we have been waiting to find out what e-cigarette-specific PMTA requirements are so that we may prepare. There is a considerable difference between expedited EU-like requirements, which take months to prepare for, vs, full PMTA, which takes years.